REMARKS

This Amendment and Response is filed in response to the Office Action dated October 23, 2007. Claims 1-33 and 45-49 are pending. In this Amendment, claim 45 is amended. No new matter is added by this amendment.

Objections to the Specification

In the interest of expediting prosecution, the amendments to the specification address the objections raised regarding new matter.

Claim Rejections – 35 U.S.C. 112

Claims 3 and 28 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. These claims recite, in part, "wherein the fatty alcohol component is included at a percentage weight level of the total film sufficient to cause the film to change from a solid to a liquid within a temperature range of 20 °C or less."

The Office Action argues that the specification does not clearly describe how to determine the percent fatty alcohol necessary to achieve the desired melting range, and therefore the subject matter of claims 3 and 28 is not described in the specification in such a way to reasonably convey to one of skill in the art. Applicants respectfully traverse.

The specification includes language identical to the claim language of claims 3 and 28 at page 10, lines 3-5. The specification also includes preferred percentage weight levels of the fatty alcohol component of the total film, such as 20 to 50 wt-% at page 10, lines 22-23. The examples section starting at page 23 of the specification also provides a description of including stearyl alcohol in the film at 30 wt-% and 35 wt-%. Each of these examples would guide one of skill in the art in determining how to make a composition according to claims 3 and 28 using a fatty alcohol. Inclusion of any fatty alcohol at the amounts specified in these examples would result in a film that would change from a solid to a liquid within a temperature range of 20 °C or less.

Accordingly, Applicants respectfully submit that claims 3 and 28 comply with the written description requirement.

Claim Rejections – 35 U.S.C. 103

Claims 1-33 and 45-49 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 7,132,113 to Zerbe in light of U.S. 2003/0118653 to Chen and in view of U.S. 7,153,531 to Engleson. Applicants respectfully traverse the rejection and request reconsideration of the claims in light of the comments herein.

Common Elements of Independent Claims 1, 25 & 33

Claims 1, 25 and 33 all specify that a film results from a coating of a composition of hydroxypropyl cellulose (HPC) and a fatty alcohol component. In claim 33, the fatty alcohol component is specifically described to be stearyl alcohol. Claims 1, 25 and 33 also specify that the film is thermoplastic.

The present application defines the term "thermoplastic" at page 5, lines 9-17 as follows:

> By use of the term "thermoplastic", what is intended is a polymer that softens and flows when exposed to a selected level of heat above room temperature and returns to its original rigid condition when cooled to a selected temperature, for example room temperature.
>
> In addition, a thermoplastic material can be softened and solidified without undergoing an appreciable chemical change if the temperature of the material does not exceed some temperature, such as 275 °F (135 °C). For example, a thermoplastic material does not degrade or char when heated to a temperature of 135 °C or below.

Because the film is thermoplastic, it may be extruded in a faster manufacturing process than is possible with conventional cast and cure films. As described in the present invention at page 21, line 27 to page 22, line 1, "After extrusion at an elevated temperature, the coatable composition quickly cools to a non-tacky state. It is not necessary to dry the film to drive off moisture or solvents. It is not necessary to apply heat to the film and circulate air for the extruded film to become non-tacky."

This manufacturing process advantage is achievable because the film is thermoplastic.

Arguments relating to Independent Claims 1, 25 & 33

Applicants respectfully submit that:

- The combination of references does not teach a thermoplastic film.
- There is no motivation for a combination of the HPC from Zerbe and the fatty alcohol from Chen, and in fact, Zerbe and Chen teach away from their combination.

In addition, there are many other distinctions between the claims and the cited references. However, Applicants remarks will focus on the reasons listed above for patentability.

The combination of references does not teach a thermoplastic film

Applicant has examined the Office Action, the locations of the references mentioned by the Office Action, the figures and other text of the three references, and can find no discussion of the film produced being thermoplastic. There is no discussion of this claim element in the Office Action.

Zerbe describes a cast and cure film forming method at column 6, lines 15-44. After coating, the film is dried in an oven to drive off the water of the composition. (Zerbe, Col. 6, line 29.) Chen describes a film that has a mucosal surface-coat-forming inner layer disposed between two moisture barrier coating layers. (Chen, Abstract, par. 28 and many other locations.) Only the composition for the moisture barrier coating layers is described as including a "moisture barrier modifier" such as a fatty alcohol. (Chen, par. 73-75.)

Zerbe's example shown at column 6, lines 3-13 shows a surfactant, Tween 80, included at a level of 3-4% of the final coating solution.

If the film of Zerbe were modified by adding a fatty alcohol as a surfactant to the composition, as allegedly taught by Chen, then the resulting film would still not be thermoplastic. Zerbe teaches a film that includes hydroxypropyl cellulose and a modified starch as providing a rapid disintegration of the film upon contact with moisture. (Zerbe, Abstract; Col. 2, lines 53-56 and many other locations.) Because of the content of modified starch in the coated film composition of Zerbe and because it is formed in a cast and cure process, the film cannot be softened and re-solidified without undergoing an

appreciable chemical change. Instead the starch would be chemically changed if heated to a high enough temperature to soften the film composition of Zerbe. Hence, even with the addition of a fatty alcohol to the composition, the resulting film would not be thermoplastic because of the presence of starch.

Zerbe describes that the starch is essential to the polymer base of the film, stating at Col. 4, lines 26-31, "An attempt to replace the starch in the polymer base completely by film-forming agents such as cellulose gum or gelatin to achieve better film properties was unsuccessful. The resulting film properties were poor, indicating that the presence of a modified starch in the film is required to achieve the desired film properties."

As a result of the presence of starch and the teaching in Zerbe that starch is essential, there is no reasonable expectation of success in achieving a thermoplastic film with desirable film characteristics by the combination of Zerbe and Chen as described in the office action.

There is no motivation to combine Zerbe and Chen, and in fact, Zerbe and Chen teach away from adding a fatty alcohol to the film composition of Zerbe.

The Office Action states that Zerbe does not disclose the use of fatty alcohols, but suggests or motivates the use of surfactants or other film forming polymers, and refers to Col. 3, lines 41-46 of Zerbe. (Office action dated 10/23/2007, page 5, first paragraph.) At Col. 3, lines 41-46, Zerbe states, "The flavored films may contain other ingredients, including surfactants, wetting agents, other film-forming polymer, and other ingredients. In certain applications, it may be desirable to increase the wettability of the film by adding surfactants."

It is clear from this passage that Zerbe teaches that surfactants may be added in order to increase the wettability of the film. Applicant respectfully submits that a suggestion to use surfactants to increase the wettability of the film of Zerbe does not provide motivation to add a fatty alcohol to the composition of Zerbe. Fatty alcohols are described in Chen as being used to provide a moisture barrier layer. Chen mentions cetyl or stearyl alcohol as one of many examples of a "moisture barrier modifier" at paragraph 75 that are included in the moisture barrier coating layers. In addition, these ingredients

are not mixed into the coating solution for the entire film, but are only provided in the outer layers. Therefore, the motivation to combine cited by the Office Action does not provide any motivation to add a fatty alcohol to the composition described in Zerbe. Accordingly, the Office Action does not provide a logical motivation to combine and the rejections relying on a combination of references should be withdrawn.

In fact, the teachings of Chen and Zerbe teach away from adding a fatty alcohol to the composition of Zerbe. Chen describes a film that has a mucosal surface-coat-forming inner layer disposed between two moisture barrier coating layers, and only the composition for the moisture barrier coating layers is described as including a "moisture barrier modifier" such as for example a fatty alcohol. (Chen, par. 73-75.) Chen describes some of the problems of prior art films that exhibit "instant wettability" which are solved by the moisture barrier coating layers. For example, patients with sweaty hands may experience difficulty handling films that exhibit instant wettability and that such films have limited shelf life. (Chen, par. 7.)

Zerbe, on the other hand, is concerned with rapid disintegration even at low levels of moisture. See, for example, Zerbe at col. 2, lines 53-57, stating that, "It has been discovered that a combination of hydroxypropyl cellulose and a modified starch provides improved solubility properties that enable rapid disintegration of the film in contact with even low levels of moisture. The improved rapid disintegration properties of the flavored films of this invention are believed to be attributable to the excellent properties of the modified starch as a disintegrant."

Zerbe's design which enables rapid disintegration with low levels of moisture teaches away from the addition of a moisture barrier modifier that serve as a moisture barrier.

For these reasons, independent claims 1, 25 and 33 are patentable over the prior art. Since dependent claims 2-24 and 26-32 are dependent on claims 1 and 25 respectively, and therefore include all of the requirements of their independent claim, claims 2-24 and 26-32 are also patentable for at least the same reasons. Accordingly, a notice of allowance is respectfully requested.